# **Participation Process**

# 1. What is the eligibility requirement for agencies to participate in the COVID-19 antigen testing program?

 Eligibility: Agencies and organizations that have a need to conduct surveillance COVID-19 screening in congregate settings

### 2. Are permission slips required to administer tests on individuals?

- Permission slips are not required for individuals over 18 years old
- Permission slips for individuals under 18 years old are required unless those minors are in state custody; agencies **must** follow applicable State and Federal laws when testing minors. You can find a sample permission slip within <u>TEA's Public Health Orders Card</u> which lays out all the basic information needed to register an individual for a test.
  - Much of the information provided on the permission slip will be needed to register an individual for a test.

# 3. Do we have to use the tests in a specific way or on specific populations?

It is recommended that agencies and organizations conduct testing in two ways:

### Targeted Testing

- Test administrators may conduct testing on employees and individuals who present symptoms of COVID-19
- All test administrators must receive a parental authorization form for any individual under 18 years of age to be tested unless that minor is in state custody, in which case the agency must comply with all applicable State and Federal laws.

#### Screening

- Agencies may conduct testing on all employees and individuals as tests are available or on specific groups of employees and individuals who may be more at risk.
- Each agency will, however, determine the testing strategy that will meet the needs of their organization within the following limitations:
  - All testing in agencies as a part of this program will be conducted voluntarily unless affected persons are in state custody;
  - Testing shall not be a condition of employment;
  - Tests will only be conducted on employees of the agency and persons in their custody;
  - All individuals conducting the testing will have complied with the training requirements;
  - Individuals tested will not be charged for the test; and

 Federal and State regulations require that all test results will be reported through the app.txrapidtest.org application or through the CLIA (Clinical Laboratory Improvement Amendment) waiver process.

### 4. Can we require an employee to take a COVID-19 Test?

 Agencies cannot mandate the use of the COVID-19 Antigen Tests on their employees, but they can mandate testing on persons in their custody (i.e. prisoners) when it is allowed by State and Federal law.

#### 5. Can relatives of employees be tested?

You must be an employee of the agency to be eligible to receive testing.
 For every positive case, a whole household is potentially affected. Please refer those individuals to TDEM and DSHS for information about COVID-19
 Test Collection Sites

### 6. Can we charge employees to take this test?

 No. These tests are being provided free of charge from the federal government, and agencies cannot charge for administering the tests.

### 7. How long is this testing program slated to run?

The program duration will be dependent on the number of COVID-19
 Antigen Test kits that are ultimately provided by our federal partners and the level of participation from agencies and organizations.

# 8. Is the Agency responsible for contact tracing of the tests administered?

 Agencies should work with their local health authority to support contact tracing requirements for individuals who test positive.

#### What kind of test is this?

# 1. What type of tests will be provided by the state? Who is the manufacturer?

The State is using COVID-19 Antigen Tests. These tests can be administered through a nasal swab and deliver results in 15 minutes or less. The State is working with multiple manufacturers to obtain the quantities of antigen tests required to meet agency needs.

# 2. What are the differences between an antigen, PCR, NAAT and antibody test?

 The antigen tests identify the virus by detecting the proteins from the virus.

- The molecular test (RT-PCR and NAAT) detects the virus's genetic material to see if you have an active coronavirus infection.
- An antibody test looks for antibodies that are made by your immune system in response to a prior COVID infection or the COVID vaccine.

# 3. Does an agency or organization need to obtain its own Clinical Laboratory Improvement Amendment (CLIA) authority to administer the tests?

The Texas Division of Emergency Management (TDEM) has obtained a CLIA waiver (#45D2193699) which allows for testing at multiple locations, including agencies across the state. TDEM's CLIA information, along with the provider of record, will automatically populate in the test registration system and should not have to be manually entered by test administrators.

# 4. Is there an expiration date or shelf life for the COVID-19 Antigen Tests?

Tests have an expiration date that is printed on the outside of each box of test kits. Review the specific information included with each kit for proper storage temperatures and conditions. Be aware that testing kit expiration dates are often extended with approval by the vendor and FDA. Check the TDEM COVID-19 Antigen Testing website for expiration date extension information.

#### 5. How accurate is this type of test?

- Antigen tests are approximately 96% accurate when returning a +Positive result at a test window of 3 to 7 days
- Antigen tests carry an approximate 20% chance of returning a false –Negative result

# 6. Could this rapid test be used to shorten the 14-day quarantine period, or does the 14-day quarantine with close contact still stand as outlined by CDC regardless of the test result?

 A negative test cannot be used to shorten the stay-at-home period for an asymptomatic close contact because that stay-at-home period covers the incubation period of the virus. During the entire 14-day quarantine period, an individual could potentially test negative and not have symptoms but still be incubating COVID-19.

# **Training**

#### 1. Do test administrators have to be medically trained?

 No; however, individual test administrators must complete the required training and report all results as required by Texas DSHS guidelines and the Governor's Executive Order No. GA-10.

### 2. How do I obtain certification training?

- Login and register for <u>www.preparingtexas.org</u>
- Complete the COVID-19 Antigen Testing Course corresponding to the specific manufacturer's test in use at your agency

# 3. I registered for a COVID-19 Antigen Test Training, but the links are not active for the course. How do I access the course?

 Once you are registered for the course, click on the home button at the top left of the page. On the Home screen, you will see a list of "Registered Online Courses. Your COVID-19 Antigen Test course should be listed and you will click on the link "Go To" beside the COVID-19 Antigen Test course to access the training.

#### 4. Who is the Test Coordinator?

 Test Coordinator: Each participating agency or organization will identify one Test Coordinator to coordinate the testing at the agency and serve as the point of contact for TDEM.

### 5. Who will be administering the tests?

- Test Administrator: Only a certified test administrator is authorized to conduct the COVID-19 Antigen Test
- Test administrators will be determined by the Test Coordinator. A test administrator may be any individual identified by the agency which completes the required training and submits all testing results as required by state and federal law
- The individual(s) identified as Test Administrators by agencies will need to complete the training course for the COVID-19 Antigen Test used on www.preparingtexas.org. Upon successful completion, the test administrator's information will be automatically loaded into the reporting system within one hour, and they will be ready to begin testing.

# 6. Do we need to have a doctor's guidance or permission to perform these tests?

There is a physician serving as the provider of record for the COVID-19 Antigen Tests. This information will be included in the data reported to DSHS on each individual's information and test results that are entered into the https://app.txrapidtest.org/ portal or through the CLIA waiver reporting process by test administrators.

# 7. Can I contract out with a 3rd party provider (clinic, outside vendor) to perform our testing program?

 Each agency can determine the testing logistics that make the most sense for them; however, third-party providers are not allowed to collect a fee or copay for performing these services.

### 8. How many tests can be administered at once?

 Testing will largely be dependent upon the availability of test administrators identified by the agencies and the testing logistics put in place at the local level.

### **Testing**

# 1. Can employees enter the required information before they come in for a test?

- Yes. Have employees over 18 years of age go to https://register.txrapidtest.org
- They will need to fill out the information required, and press submit. A QR code will be created that contains the information necessary to register. They may print out the QR code or take a picture on their phone to bring to the testing location.
- Legal guardians of employees under 18 years of age must also provide a signed permission slip. No permission slip is required if the minor is in state custody, provided the agency follows all applicable State and Federal laws.

# 2. If a test administrator who successfully completed the training does not have a password for app.txrapidtest.org, how can they get one?

Select the "forgot password" link and follow the instructions.

#### 3. How long does the test take?

 The COVID-19 Antigen Tests in use take 15 minutes or less to return a result; refer to the documentation included with the specific test in use for proper testing administration and interpretation times.

# 4. How long can I wait to insert the nasal swab after a sample has been taken?

 Refer to the documentation included with the specific test in use for proper testing administration and interpretation times

#### 5. If I test (+) positive, do I have COVID-19?

- Presumptive Test: This test is only an indicator of the presence of the COVID-19 virus
- A formal medical evaluation and certified laboratory verification would be necessary to indicate a confirmed infection
- Presumptive-positive results also do not rule out bacterial infection or coinfection not related to COVID-19.

#### 6. Does this test identify the common cold or strep throat?

No: This is a specific test for the COVID-19 virus SARS-CoV2

### 7. Can I open multiple tests at a time??

 Only open the COVID-19 Antigen Tests when you are ready for test administration. Refer to the documentation included with the specific test in use for information on potential time limits on test administration following opening of test packaging.

#### 8. What do I do if I think the test is defective?

- Contact Customer Support for the specific test in use at your site.
- Binax Antigen Test: Abbott Diagnostics Scarborough, 1-800-257-9525, ts.scr@abbott.com
- CareStart Antigen Test: Access Bio, Inc., info@accessbio.net

### 9. Who is liable if the testing injures an employee?

Consult your agency's legal counsel.

# 10. Are the used test kits and used PPE considered medical waste for disposal?

- The used Test Kits are considered Medical Waste and must be disposed of according to TCEQ guidelines
- PPE used while handling and administering the rapid COVID test kits are not considered medical waste.

### 11. Can these tests be used on asymptomatic individuals?

 Yes. The Center for Medicare & Medicaid Studies will allow testing on asymptomatic individuals during the public health crisis.

# Reporting

#### 1. How are test results shared with the individual being tested?

- As part of the test registration process, the individual or their guardian's phone number and email address can be entered into app.txrapidtest.org.
   Once the test results are put in the system by the test administrator, a text message and email are auto-generated to notify the individual.
- There is no auto-generated report to let the agency know who and when someone tested positive. Test administrators will also have access to this information as they are inputting the test results and should work with their agency to determine if an additional process is needed.

### 2. What happens when someone tests positive?

- This testing is a process that will be determined at the local level. It is recommended that agencies follow public health guidance from DSHS and the CDC and that any positive case be quarantined and seek guidance from their Primary Care Physician
- Agencies should also contact the local health department to provide information on any individual who tests positive.

# 3. If an individual receives a positive antigen test result, should we direct them to get a PCR (molecular) lab-based test?

 Yes, this is a presumptive positive test and is a mechanism for agencies to immediately identify presumptive positive cases. People receiving a positive test should consider obtaining a more formal PCR (molecular) labbased test.

### 4. How is my personal information used?

- All personal Health information collected in registration and results will be handled under local, state and national privacy rules
- Individual Level registration and results from information in the registration application will only be shared with the Department of State Health Services as required by Law.
- Aggregate level information without personally identifiable information may be shared with State agencies and the public.

# 5. If an organization does not have a reporting system in place, how is the reporting system developed for TDEM accessed?

- Login and register for www.preparingtexas.org.
- Complete the COVID-19 Antigen Testing Course on preparingtexas.org specific to the test in use at your location
- Individuals who successfully complete the required COVID-19 Antigen Testing course receive login information for the testing application at https://app.txrapidtest.org. The registration process may take up to one hour before it is active. You will need this APP to report the results from each test unless you are using the CLIA waiver reporting process.

#### Results

# 1. Does the test information get shared with the local health department and DSHS or do agencies need to report these cases to the appropriate authority?

- TDEM, through our partner agency, Southwest Texas Regional Advisory Council (STRAC), will report registration of individuals tested, the entering of test results, and the report of test results to the Texas Department of State Health Services
- As required by Law, all results negative, positive, and inconclusive from testing shall be reported daily to the Department of State Health Services DSHS through the provided test portal system *Texas Rapid Test app* -<a href="https://app.txrapidtest.org/">https://app.txrapidtest.org/</a> or through the CLIA waiver reporting process.



### **Equipment**

# 1. What will we use to register/test/input information related to testing?

- Every test administrator will need a smartphone, tablet, computer, or other internet-capable smart device for the *Texas Rapid Test app* used to register and record individual test information and/or
- manually enter personal information and test results through the CLIA waiver reporting process.

### **Ordering**

# 1. What type of storage capacity is needed to accommodate these tests?

- For Binax COVID-19 Antigen Tests, there are 40 cards and test kits in a shoebox-sized box
- For CareStart COVID-19 Antigen Tests, there are supplies for 20 test kits in each box that is 9" x 6" x 3.5"

#### 2. How do I order more test kits or PPE?

 Any need for more test kits or Personal Protective Equipment (PPE) by a test administrator used only for testing purposes should be routed to your agency test coordinator.

Agencies and organizations with questions may reach out to TDEM for guidance and operational support at (512) 695-1357. TDEM can be reached by e-mail as listed below:

For questions and guidance: <a href="mailto:antigentesting@soc.texas.gov">antigentesting@soc.texas.gov</a>
For test kit supply requests: <a href="mailto:resupply@tdem.texas.gov">resupply@tdem.texas.gov</a>